

Drug Enforcement Administration Pharmaceutical Industry Conference

A Wholesale Distribution Diversion Control Program

October 15, 2009

**Chris Zimmerman
Vice President - Corporate Security & Regulatory Affairs
AmerisourceBergen Corporation**

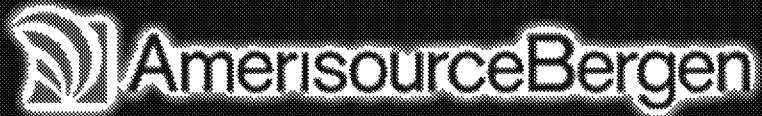
Copyright 2009 – AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation

HIGHLY CONFIDENTIAL - ATTORNEYS EYES ONLY
CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

ABDC001841
ABDCMDL00037206

DEF-WV-00002.00001

DEF-WV-00002



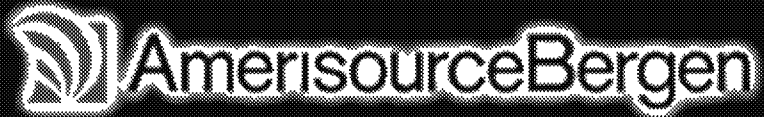
Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

1301.71(a) - "All applicants and registrants shall provide **effective controls** and procedures to **guard against** theft and **diversion** of controlled substances."

Distributor Response: Develop policy to

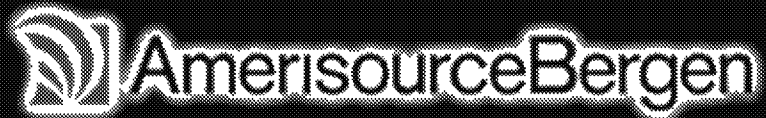
Copyright 2009 – AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation



ABC's Diversion Control Program

- ▶ Prior to June 2007
- ▶ After June 2007
- ▶ September 2007 – ABC Presentation to the DEA Pharmaceutical Industry Conference, Houston TX
- ▶ October 2009

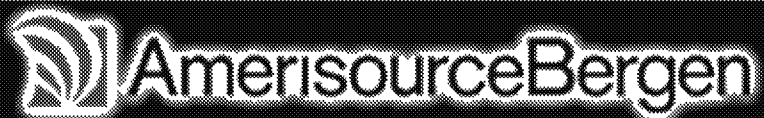
Copyright 2009 – AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation



ABC's Diversion Control Program

- ▶ “Know Your Customer” Due Diligence
- ▶ Order Monitoring Program (OMP)
- ▶ Investigations
- ▶ Education and Training

Copyright 2009 – AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation



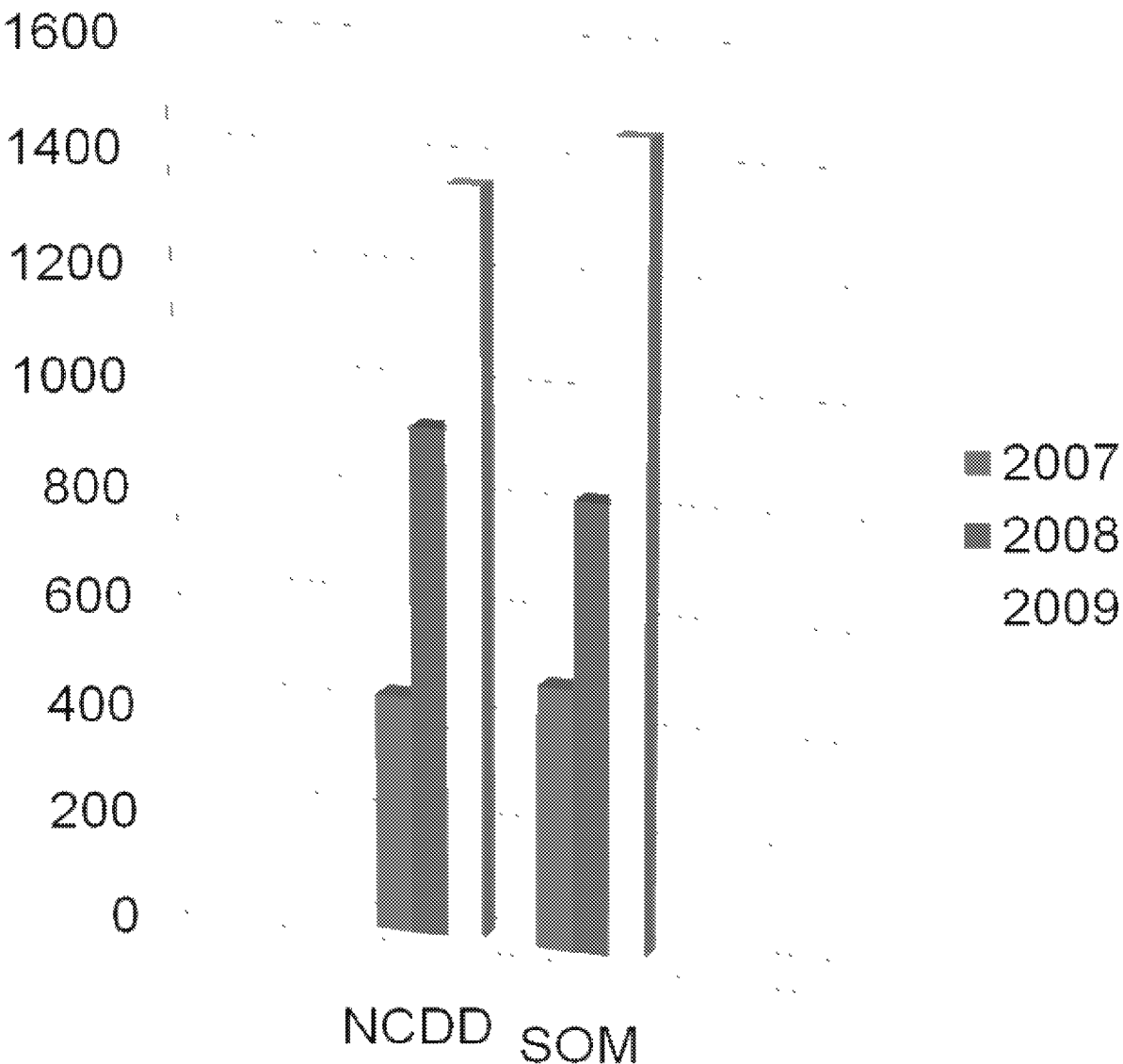
New Customer Due Diligence

- 2007 – 438
- 2008 – 929
- 2009 – 1,356

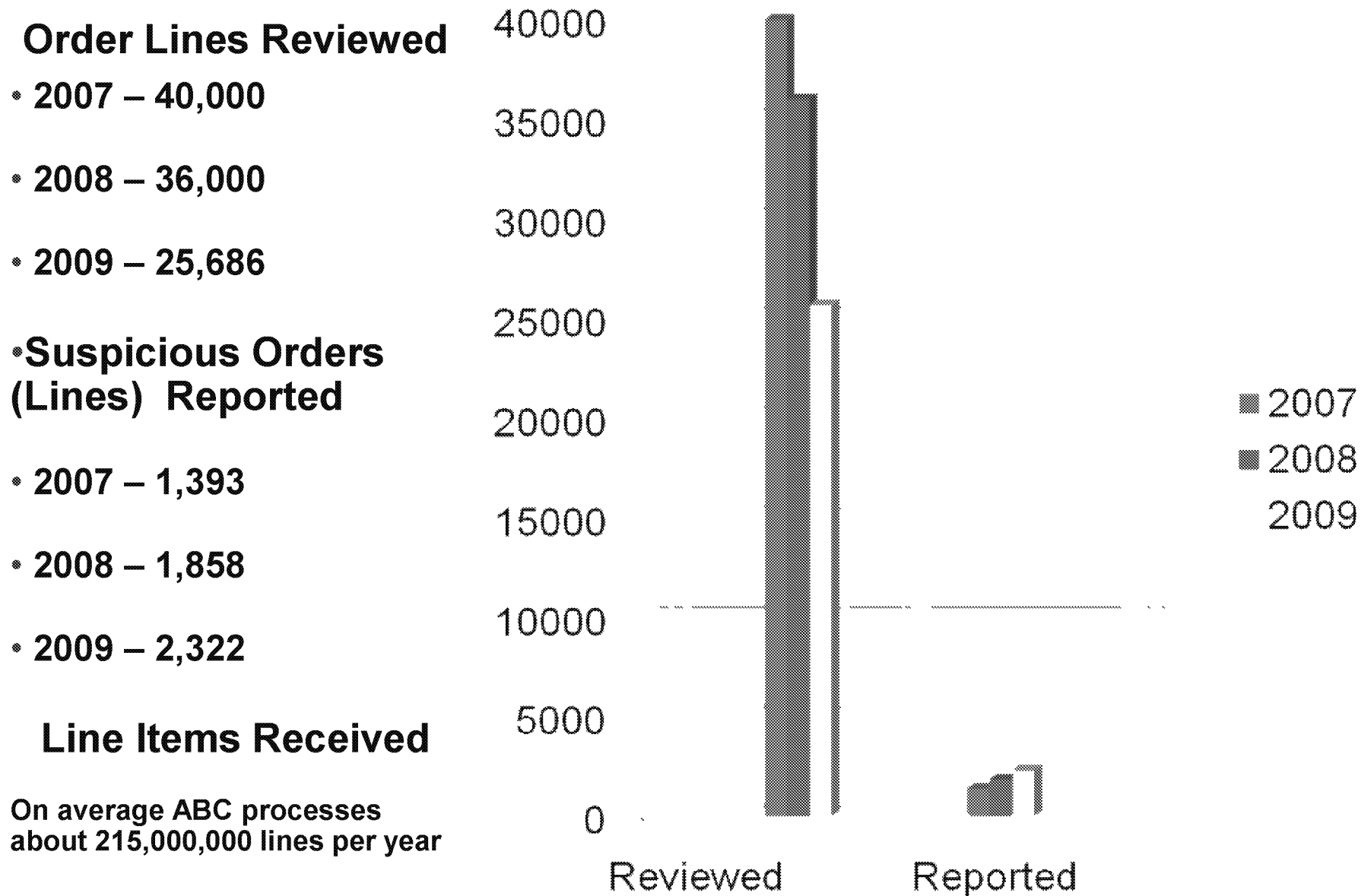
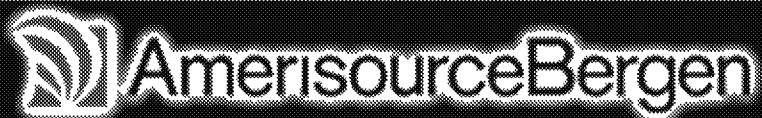
Number includes review of existing customers.

Suspicious Order Monitoring Investigations

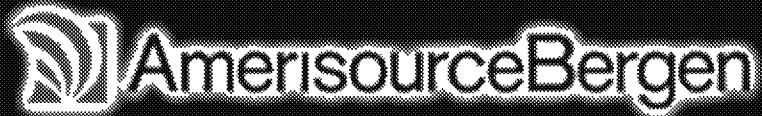
- 2007 – 483
- 2008 – 822
- 2009 – 1,453



Copyright 2009 – AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation



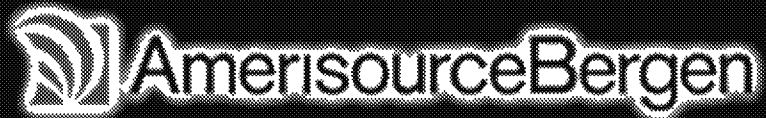
Copyright 2009 – AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation



Internal Departmental Changes

- ▶ A dedicated Diversion Control staff, consisting of a manager, two diversion investigators, and one investigator/analyst was implemented.
- ▶ This staff was given the responsibility for the Order Monitoring Program, Suspicious Order Investigations, New Customer Due Diligence Investigations, targeted pharmacy visits, trending reports, and customer and employee/customer education.
- ▶ On a monthly basis, the diversion control staff reviews about 3,000 orders.
- ▶ Approximately 6% or 180 orders per month are investigated and subsequently reported to the DEA as suspicious orders. These orders are not shipped.

Copyright 2009 – AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation



Diversion Control – An Ever Evolving Program

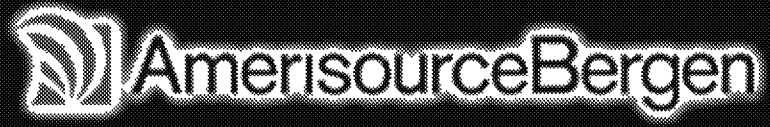
Then

- ▶ No dedicated DC staff
- ▶ 2 page questionnaire
- ▶ Basic due diligence
- ▶ Hydrocodone and Alprazolam
- ▶ Internet sales
- ▶ Limited interaction with pharmacy
- ▶ Few compliance specific visits
- ▶ Limited guidance provided

Now

- ▶ Manager, 2 investigators, analyst
- ▶ 5 page questionnaire
- ▶ Enhanced due diligence
- ▶ High risk CS / Tramadol & Soma
- ▶ Pain Management / Dispensing docs
- ▶ Regular interaction with pharmacy
- ▶ Regular compliance specific visits
- ▶ Model Policies & Procedures

Copyright 2009 – AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation



Questions?

Copyright 2009 - AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation

HIGHLY CONFIDENTIAL - ATTORNEYS EYES ONLY
CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

ABDC001849
ABDCMDL00037214

DEF-WV-00002.00009